Exhibit K

IN THE UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	MDL NO. 2327 HON. JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

THIS DOCUMENT RELATED TO THE FOLLOWING CASES IN WAVE 1 OF MDL 200:

Donna Amsden v. Ethicon, Inc.
Civil Action No. 2:12-cv-00960

Marie Banks v. Ethicon, Inc.
Civil Action No. 2:12-cv-01318

Harriet Beach v. Ethicon, Inc.
Civil Action No. 2:12-cv-00476

Sharon Boggs, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00368

DEPOSITION OF
PEGGY PENCE, PH.D.
MARCH 9, 2016

Karen Bollinger v. Ethicon, Inc.
Civil Action No. 2:12-cv-01215

Robin Bridges v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00651

Denise Burkhart v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01023

Myra Byrd, et al., v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00748

Sharon Carpenter, et al. v. Ethicon, Inc., et al.
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Carey Beth Cole, et al. v. Ethicon, Inc., et al.
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Angela Coleman, et al. v. Ethicon, Inc., et al.
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Fran Denise Collins v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00931
Mary F. Cone v. Ethicon, Inc.
Civil Action No. 2:12-cv-00261

Patricia Conti v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00516

Amanda Deleon et al. v. Ethicon, Inc., et al.
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Dina Destefano-Raston, et al. v. Ethicon, Inc.
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Karyn E. Drake, et al. v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-00747

Paula Fisk v. Ethicon, Inc., et al.
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Karen Forester, et al. v. Ethicon, Inc., et al.
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Sherry Fox, et al. v. Ethicon, Inc., et al.
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Susan Guinn v. Ethicon, Inc., et al.
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Sandra Wolfe v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-0335

Rebecca Pratt v. Ethicon, Inc., et al.
Civil Action No. 2:12-cv-01273

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Deposition of PEGGY PENCE, PH.D., taken on behalf of the Defendants, before Kristi Johnson, CSR No. 12585, commencing on Wednesday, March 9, 2016, at 9:12 a.m., at 100 Bayview Circle, Suite 5600, Newport Beach, California, pursuant to Notice of Taking Deposition.

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I N D E X

WITNESS: PEGGY PENCE, PH.D.

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NEWPORT BEACH, CALIFORNIA; WEDNESDAY, MARCH 9, 2016
9:12 A.M.

PEGGY PENCE, PH.D.,
called as a witness, having been first duly sworn, was examined and testified as follows:

EXAMINATION
BY MS. SUTHERLAND:
Q. Good morning.
A. Good morning.
Q. Would you please tell me your full name?
A. Peggy Jo Clark Pence.
Q. Dr. Pence, what is your address?
A. 1533 Miramar Drive, Newport Beach, California 92661.
Q. Is that your business address?
A. It is my home address as well as I have an office there as well, and then I have a satellite office in Newbury Park.
Q. You used to live where before?
A. Newbury Park.
Q. So you still have that. Is that where your employees are?
A. We all work remotely. It's an address for a

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satellite office, but we're all working remotely from our homes at this point in time.
Q. Are you still teaching?
A. Yes.
Q. Are you currently teaching or about to start?
A. My class starts April 5th.
Q. How long will that be?
A. It goes through the end of June.
Q. And remind me what you teach?
A. Clinical trials and quality assurance. Biology 516, if I recall correctly, is the number. It's a graduate-level course for students that are working on their master's in biotechnology at California State University, and I teach that course at the Channel Islands campus.
Q. As part of the class you teach, I would assume you include teaching on FDA regulations?
A. Yes, I do.
Q. Do you also include teaching on Global Harmonization Task Force guidances?
A. Yes, I do.
Q. How long have you been including the GHTF guidances as part of your course material?
A. Without checking back on my PowerPoint slides, I can't tell you exactly when I began doing that. This

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will be my sixth year to teach this specific course.
Q. Did you teach on GHTF last year?
A. Yes.
Q. The year before that?
A. I don't recall without checking back on my notes and PowerPoint slides because I update them every year. Let me say I suspect, to the best of my recollection, that I did because I have always also taught an international conference on harmonization, which is relevant to drugs, and the GHTF is analogous to the international conference on harmonization but for medical devices, GHTF for medical devices. And I teach about both medical devices and drugs. So I suspect I have been doing it for several years. I just would have to -- to the extent to which I have been talking about it, because there's a lot to cover, and essentially, I have 12 weeks to cover a tremendous amount of material. So the extent to which I addressed it, I don't recall specifically as I sit here today without checking back thinking back to two years ago.
Q. I'm sorry, the last part of that was?
A. You had asked me about two years ago did I teach it.
Q. So the answer was you think you have taught it longer than two years ago?

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A. This is my sixth year to teach this particular class.
Q. You think you have taught on GHTF longer than the last two years, but you would have to check to be sure. Would that be fair?
A. Yes.
Q. On your GHTF course material, do you use specific guidances?
A. I give them guidances to review as part of -- I present certain information in class, and then for various reading material to support what I present to them in class, I give them various guidances, whether it's drug or medical device related, and that would include GHTF guidances. And, for example, they always have an individual -- at least one, if not more, individual project assignment that they have to research and present prior to the end of class, and some of those are drug related, some of those are medical device related. I give them as resource materials the guidances and instruct them on their own as well to review those guidances and incorporate those into their thinking and their conclusions, their analyses of the problems that I give them to report on.
Q. Now, do you typically, if you can recall, utilize specific GHTF guidances? In other words, could

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you name them for me, the ones you use in class?
A. I'd have to check back to tell you specifically the ones that I use in class, but more than likely, they would be the essential principles of safety and performance. They would have to do with the clinical evaluation, labeling guidances, conformity assessment guidances. Also, I usually have a guest speaking that comes in and talks about quality management systems, so it would include the guidances on quality management systems that they would have as well, clinical investigations.
Q. Do you have a syllabus that you have already put together for the upcoming class that you're going to teach in April?
A. Not yet. Been too busy.
Q. Do you need to get working on that?
A. Yes. I'm waiting on the contract, and then it will happen in the next couple of weeks.
MS. SUTHERLAND: I'm going to hand you what I marked as Depo Number 1 and that's your notice.
(Defendant's Exhibit 1 was marked for identification by the court reporter.)
BY MS. SUTHERLAND:
Q. Did you bring some documents with you today?
A. I did.

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Q. Can I take a peek at what you brought? Just this binder?
A. No. I have others, too, in case you need them.
You were asking about GHTF documents. Those are ones that have been referenced in my report. I also brought FDA proposed orders and the reclassification of transvaginal mesh for pelvic organ prolapse repair. This is the document, the compilation of the documents that are footnoted in my Prosima report.
Q. Ethicon documents?
A. Ethicon or other documents that are referenced, publications that are referenced in footnotes in the body of my main report.
Q. Now, if I want to get copies of your binders, do you remember how we have done that before?
A. We have done it two ways. Last time they were taken and returned to me, but it took a while to get them back, so I'm not sure why it took so long. I will need them for reference. If they were to be taken, could they be returned quickly? That's how we did it the last time.
Q. If we could -- we'll work with Golkow to make sure we have a quick turnaround. Would that be okay with you if Kristi took them and then we made an effort to be sure we got them back to you?
A. Yes. We can either do that or I can take them

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and have them printed, but it's probably --
MR. KUNTZ: Whatever you want to do. I think the last depo we turned them around pretty quick.
THE WITNESS: It took them a while to get them back to me. I think there was confusion about my address. If we can just get them back quickly.
BY MS. SUTHERLAND:
Q. While we're here, give me again the street address where you want them shipped back?
A. 1533 Miramar Drive, Newport Beach, California 92661.
Q. Would you mind if I put stickers on them, or would you like me to tape them, for marking the binders as exhibits?
A. Whatever you want to do.
MS. SUTHERLAND: I'll stick a sticker on the outside, and I'm sure you can scrape it off later.
I'll mark as Exhibit Number 5 your white binder called "Prosima Systems" that is listing your February expert report and your March supplemental report, and it appears there are three tabs in it and a number of colored tabs, five tabs, and supplements.
(Defendant's Exhibit 5 was marked for identification by the court reporter.)
THE WITNESS: That's the supplement and the

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exhibits to the supplement.
BY MS. SUTHERLAND:
Q. That will be Number 5, and I will hand that back to you.
Number 6 I will mark -- I knew this looked familiar with Cavness marked out and MDL marked on there.
A. My staff knows that Cavness was Prosima. Everything that's Prosima, they write Cavness on it.
MS. SUTHERLAND: So I will mark as Exhibit Number 6 your orange binder that has tabs in yellow with numbers delineated on the side which would reflect footnote numbers?
THE WITNESS: Yes.
MS. SUTHERLAND: And if we could, when we get those copies made, we'll have the tabs the same that delineate the numbers.
(Defendant's Exhibit 6 was marked for identification by the court reporter.)
BY MS. SUTHERLAND:
Q. There are orange tabs. Those just separate the actual documents?
A. The pages of the report. The pages of the report -- the way Christine put that together was the pages of the report, and then behind the pages of the report is the documents that are referenced in the

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footnotes for that page.
Q. Very coordinated. I see what you're saying. I'll hand that back to you.
The next binder that I will mark as Number 7, which is just a blue binder that's not labeled and has an article in the front flap as well as articles in the binder.
(Defendant's Exhibit 7 was marked for identification by the court reporter.)
BY MS. SUTHERLAND:
Q. This just looks to be primarily FDA documents?
A. Yes.
MS. SUTHERLAND: Then Exhibit 8 is a blue binder with white labeling GHTF final guidance documents.
(Defendant's Exhibit 8 was marked for identification by the court reporter.)
BY MS. SUTHERLAND:
Q. And am I to understand these are the GHTF guidance documents in your Prosima report?
A. Yes, there are initial ones in there as well that are not necessarily footnoted in my report.
Q. Do you know which ones that are additional that are not in your report?
A. I could go through and probably tell you.
Q. If you can do that quickly, I'd appreciate it

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just so I know.
A. Sure. To the best of my recollection as I sit here today.
Q. I understand. I understand.
A. The clinical evidence, I would have to double check, but the "Postmarket Clinical Follow-Up Studies," I would need to check on that. I believe the "Review of Current Requirements on Postmarket Surveillance."
Q. You are listing for me the ones that are not listed in your report; is that right?
A. To the best of my recollection without cross referencing my report. I can go through them individually and check them pretty quickly.
Q. I'm running through your footnotes as well just to double check the ones you have called out.
A. They would be predominantly referenced in the Exhibit 1. They might be in other places as well, but specifically, in Exhibit 1.
I do note that it looks like I did not include in here the "Implementation of Risk Management Principles." It doesn't look like I brought a copy of that one in the binder.
I'm sorry, I do have "Postmarket Clinical Follow-Up Studies." It is referenced in my Exhibit 1 to my supplemental report.

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Q. What footnote is that?
A. That is in Exhibit 1. It is Footnote 41 on page 8. Let me see if there are any others. On page 11 of my Exhibit 1, I did not include copies in the binder of the GHTF roles and responsibilities, guiding principles, and operating procedures. I did not include copies of those guidances.
Q. My original question was were there guidances in the binder that you saw that were not listed in your report?
A. Yes.
Q. Just remind me again, what were those?
A. The clinical evidence I don't believe is referenced and the "Review of Current Requirements on Postmarket Surveillance," from a quick review, doesn't appear to be included.
MS. SUTHERLAND: I'm going to hand you what I have marked as deposition Exhibit Number 2.
(Defendant's Exhibit 2 was marked for identification by the court reporter.)
BY MS. SUTHERLAND:
Q. If you would, identify that for me.
A. This appears to be my expert report of February 1st, 2016, on Prosima.
Q. That has five exhibits to it?

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A. Yes. Shall I check to make sure they are all here?
Q. I think they are. It never hurts to check. I think they're separately stapled so you can tell easily.
A. Yes, there are five exhibits.
MS. SUTHERLAND: I am going to hand you what I have marked as deposition Exhibit Number 3.
(Defendant's Exhibit 3 was marked for identification by the court reporter.)
BY MS. SUTHERLAND:
Q. Now, that is what was provided to us in March as your supplemental report on Prosima and Prolift; is that correct?
A. That is correct. I'm just checking to make sure both exhibits are attached. Yes, they are.
Q. What was the date of that report, Dr. Pence?
A. March 3rd, 2016.
MS. SUTHERLAND: I may ask you some questions about that. I'll just put this caveat that I'm not going to waive my objections to the late filing of that after the plaintiff's expert deadline, be that as it may for whatever good that does.
MR. KUNTZ: I'll have to --
MS. SUTHERLAND: Say you would object?
MR. KUNTZ: -- pipe in. I think the rules

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allows -- frankly, I think it just organized it and tailored it to what we were going to talk about were issues. I don't think there's any new opinions. It is what it is, I agree.
BY MS. SUTHERLAND:
Q. Is there anything in your supplemental report that you're relying on that was not available to you before February 1, 2016?
A. I had not had an opportunity to review Dr. Weisberg's late 2015 testimony with regard to the label changes for Gynemesh PS.
Q. Do you know when he was deposed?
A. If I recall, it was in November.
Q. Twelve and thirteen?
A. Yes, of 2015.
Q. Do you know if the transcript was available for that prior to February 1, 2016?
A. I anticipate it was.
Q. When did you get a copy of it?
A. I don't recall the exact date.
Q. Did you get a copy of it in March?
A. No, I did get it prior to that.
Q. Did you get a copy of it before your February 2016 Prosima report?
A. I don't recall specifically as I sit here

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today.
MR. KUNTZ: I'll have to make a record because I have to. I don't think that that -- my position is that it's just reliance materials that further support her opinions that she's been given for four or five years in this litigation. It's not a new opinion. In fact, Ethicon changed the IFU to list things she's been saying for three or four years that should have been in the IFU. I don't think it's a new opinion. I think it's supplemental materials that support her opinion, and the rules allow you to file supplemental reliance list 30 days before trial.
BY MS. SUTHERLAND:
Q. Other than Dr. Weisberg's deposition transcript, were there any other materials that weren't available to you before February 1, 2016, in your supplemental report?
A. Of course, along with his -- Dr. Weisberg that is -- deposition, the exhibits that were attached to that, of course, but as I stated in my supplemental report, there are no new opinions. I didn't change any opinions. I just provided supplemental to my prior reports, I should say, information that I thought was additionally supportive to my opinions, my prior opinions.

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Q. I understand that. To get an answer to my question, other than Dr. Weisberg's deposition and the exhibits attached to his deposition, are there other materials that were not available to you prior to February 1, 2016, that you cite in your supplemental report?
A. No.
Q. Now, in your supplemental report, as I understand it, that applies to, obviously, the Prosima report from February of 2016?
A. Yes.
Q. And then you reference four Prolift reports; correct?
A. Yes.
Q. Now, as far as any Ethicon mesh devices to treat prolapse, are those the reports we're talking about?
A. Yes.
Q. So four for Prolift, one for Prosima, and then the supplement?
A. Yes, and two of the Prolift were supplemental reports.
Q. Now, when did you draft your supplemental report?
A. The March 3rd, 2016, one?

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Q. Yes, ma'am.
A. It would have been late February to early March.
Q. Why did you draft it?
A. Because I felt after when I reviewed -- when I had an opportunity to review Dr. Weisberg's deposition and the attachment, the exhibits, I mean to say, to that, I recognized that it was additionally supportive of my opinions because the modifications, the revisions to the labeling as regards to risk information, included information that, from my original reports dating back to 2012 for my first Prolift report, in fact, contained information that ultimately Ethicon added after they received notification from Health Canada that Health Canada was requesting updates to the labeling. And I thought that was substantiation of my opinions, and it was important to document that. In the course of doing that, I also decided to add some additional information supportive of my opinions about failure to test from other authoritative bodies.
Q. Why did you feel like you needed to add other information from other authoritative bodies in your supplemental report?
A. I thought it was important to -- I have added it in some other reports that I have done that I hadn't

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added initially, if I recall correctly as I sit here today, in my first Prolift report. And I thought it would be helpful and that I would add it as a result of that since I was updating the report, and then, of course, the GHTF information.

Q. Is the GHTF information material that was not included in your Prolift 2012 report?

A. That's correct.

Q. Was the GHTF information included in your -- I think it's 2014 Prolift report?

A. No.

Q. So the only GHTF information that you have supplied now for Prolift is your March 2016 supplemental report; is that correct?

A. Yes.

Q. Did you review any ruling by Judge Goodwin addressing the scope of your opinions before you drafted your supplemental report?

MR. KUNTZ: Objection. Vague as to time. What opinion?

BY MS. SUTHERLAND:

Q. Do you understand my question?

A. Yes, but if you'll repeat it, please.

Q. Absolutely. Let me ask it this way: Have you ever reviewed any opinion from Judge Goodwin addressing

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the scope of your opinions that he would allow at trial?

A. Yes, some time ago I did.

Q. Did you review an opinion from May of 2015 in a Boston Scientific order addressing the scope of your opinions?

A. I don't recall the date of the order specifically. If you have it, I can take a look at it and tell you if that's what I reviewed.

MS. SUTHERLAND: I'm going to hand you what I am marking as number 9.

(Defendant's Exhibit 9 was marked for identification by the court reporter.)

BY MS. SUTHERLAND:

Q. Take a look at that and tell me if that's the opinion by Judge Goodwin that you may recall reviewing. For ease of reference, your part begins around page 9.

A. I did find it, thank you. I am going through it to see if it seems like what I reviewed. This appears to be what I reviewed, if not very similar to what I reviewed.

Q. Dr. Pence, after you reviewed deposition Exhibit Number 9, or if I understand your testimony correctly an opinion similar to it, did you decide to add in information about GHTF to your reports about Ethicon mesh?

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A. You'll note that when I wrote my Prosima report, which is dated February 1st, that it has an exhibit, the GHTF information, and that is not the first report for mesh products where I included GHTF. Back, if I'm recalling correctly, in 2014, I wrote a Boston Scientific report in which I included GHTF information, and so when I wrote the Prosima report, I included the GHTF information understanding instead of FDA regulations based on my understanding of the concerns about FDA sometimes being allowed, sometimes not being allowed, and that there are other standards on which to rely. So when I was doing the supplement, I realized that I had never done that for Prolift. Prolift only has FDA information and that it was appropriate and relevant to also include the GHTF information for Prolift as well as Prosima.

Q. Would it be fair to say that you added in the GHTF information in your Prosima February 2016 report in part because of Judge Goodwin's order excluding opinions where you just rely on FDA regulations?

A. That isn't recent. Although this Exhibit 9 is dated May 2015, as I mentioned, I had previously added GHTF into a prior report understanding, back a couple years or more ago, that at least for the MDL litigation, that the FDA was not to be a part of that litigation, and there are other standards that the industry relies on

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that are relevant internationally, and in particular to the U.S. and that the U.S. has participated in establishing those standards, so that to exclude other standards was not presenting a comprehensive approach to the available evidence to support my opinions.

Q. If I'm understanding you correctly, I believe you testified that you're not offering any new opinions regarding Prolift other than what was set out in your 2012 and 2014 reports; correct?

A. That is correct.

Q. And in those 2012 and 2014 reports, what you relied on to support your opinions in part were FDA regulations; correct?

A. Yes, as a regulatory expert working in the United States.

Q. That would seem to make sense, wouldn't it?

A. Exactly, but there are additional standards, and because I am a regulatory expert working in the U.S., I initially included FDA standards. Recognizing that for certain courts that that information may not be allowed to be presented, I wanted to provide a more comprehensive and broader base for my opinions and reflect the international standards, which include much of the same types of information, but it's an international standard that substantiates my opinions.

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Q. Is it your testimony that the opinions on Prolift that you offered in the 2012 and 2014 reports, you're not relying on FDA regulations to support those opinions?
A. No, that's misrepresenting what I'm trying to say.
Q. Then let me follow up.
Is it your testimony then that, in fact, you are still relying on FDA regulations to support the opinions you set out in your 2012 and 2014 Prolift reports?
A. The best way to answer that is that both FDA regulations and the GHTF guidances support my opinions. So I'm not saying that my opinions aren't supported by FDA regulations. They are, but my opinions are also supported by the GHTF guidance documents. The GHTF -- the purpose of that was to harmonize international standards.
Q. I'll get to that. Let me get back on track. I got off my outline.
Looking back at your supplemental report, there are two exhibits to that; correct?
A. Yes.
Q. When I say supplemental report, I know you have got a TVT supplemental report I haven't marked yet. For

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now I'm focusing on the Prosima and Prolift one I marked.
There are two exhibits to that; correct?
A. Yes.
Q. One is an industry standards document that you drafted?
A. Yes.
Q. Dated March 3rd, 2016?
A. Yes.
Q. And then there's a MAUDE report; correct?
A. Yes.
Q. M-A-U-D-E, all caps. Tell Kristi what that stands for.
A. Manufacturer and user facility device experience database.
Q. Now, in your Prosima original report, the February 2016 report, you also have an exhibit that is applicable industry standards; correct?
A. I'm sorry, can you repeat that?
Q. No worries.
In your original Prosima report from February 2016, your first exhibit is also applicable industry standards?
A. Yes.
Q. Now, Exhibit 1, which is applicable industry standards for the February Prosima report, is somewhat

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different than Exhibit 1 that goes to the supplemental report; correct?
A. It has some additions.
Q. The supplemental report has some additions?
A. Yes.
Q. Within that month time frame, from February to March, why did you add in the supplement additions?
A. I felt they were helpful.
Q. Can you tell me which ones you added in?
A. We can do a comparison here. One thing I know for sure that I added was further information on the process by which the GHTF documents were developed, and that is its own section, Section 4, starting on page 11 of Exhibit 1 to the supplemental report, titled "Supplementary Information Regarding GHTF Procedures: All Decisions and Actions By Consensus."
Q. While we're on that, let me interrupt you for just a minute.
The five study groups that you list there on page 11, are those the only five study groups that GHTF had during the 20-year time frame that it was ongoing?
A. To my understanding, that's correct, yes.
Q. Now let me ask you: Do you know the makeup of any of the study groups?
A. Can you clarify what you mean by makeup?

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Q. Sure.
As I understand it, GHTF included, obviously, regulatory agencies?
A. Right.
Q. Did it include industry representatives?
A. Yes.
Q. Were consumer representatives included?
A. It was a mix of regulatory and -- it was a partnership, if you will, between regulatory and industry. For example, AdvaMed represented -- was represented in the various GHTF groups.
Q. Which ones?
A. I can't tell you specifically as I sit here today.
Q. During the whole time frame or specific times?
A. I don't have the information available to tell you specifically. I do know they participated, other industry representative groups as well participated, some specific companies. The aim was to have equal representation between regulators and industry groups.
Q. First of all, let me ask you: How do you know AdvaMed was in the study groups?
A. Because I did some of my own independent research and was able to confirm, to the best of my recollection. For example, AdvaMed was, I believe Boston

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Scientific was, to the best of my recollection, I believe Medtronic was, some of the ones I was able to find, best of my recollection, as I sit here today.
Q. How did you find them?
A. By Internet searching and trying to find information on the identity of who was in particular groups.
Q. Just trolling through the Internet, essentially, to find out?
A. Doing specifically directed searches looking to see what I could find to support that information.
Q. Now, in your searches, was Ethicon ever a member of any of the five study groups at GHTF?
A. I don't recall seeing Ethicon specifically, as I sit here today.
Q. What about J&J?
A. A lot of that information just isn't available online. I can't say if they were or were not, but they were certainly represented by AdvaMed.
Q. Were they a member of AdvaMed at the time AdvaMed was a member of GHTF?
A. I don't have that specific information as I sit here today, but certainly, AdvaMed, the working group that put together a presentation for the 2011 advisory meeting, Ethicon participated in that and that was

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through AdvaMed.
Q. That was for FDA, though; right?
A. Yes.
Q. But we're talking about GHTF.
A. Yes, I understand that, but they were certainly working through AdvaMed at that time.
Q. So let me close the loop on that.
Do you have information showing that in 2011, at the same time that Ethicon was in AdvaMed working for the FDA group in 2011, that they were also working in one of the study groups in GHTF?
Was that a convoluted question? I can ask that better.
A. Yes.
Q. Your pretext or your preface is that Ethicon was working with AdvaMed in 2011 during the whole time frame with the panel meeting and FDA in 2011?
A. Yes.
Q. Now, as I understood your testimony, you initially said that you knew that Ethicon was in AdvaMed and that AdvaMed was working with GHTF?
A. I knew that they were a member of AdvaMed. Based on the information that I have, it appears that they're a member of AdvaMed. The years of their membership, I don't have that information available as I

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sit here today.
Q. The years that AdvaMed, from what you saw, worked with GHTF, do you know those years?
A. I don't recall those specifically as I sit here today.
Q. Now, if I asked you the same questions with respect to Johnson & Johnson, do you know whether or not Johnson & Johnson was ever a member of GHTF?
A. I don't know as I sit here today. I don't have a list of all of the membership.
Q. You did say Boston Scientific; right?
A. Yes.
Q. Do you know when Boston Scientific was a member of GHTF?
A. I don't recall the date as I sit here today.
Q. Do you know which study group they might have been in?
A. I don't recall as I sit here today.
Q. I was curious on that one.
What about any other pelvic mesh manufacturer?
A. As I said earlier, the information on specific memberships and the different study groups, although I did look for it, I was unable to find a great deal of information about that, except to know as it's set out that in the membership of GHTF, that it is an equal -- it

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was, as you know, disbanded and transferred to IMDRF, which is all regulators. But during its 20-year history, the aim was to be an equal partnership between industry and the regulators internationally with the five founding members, and then there's some additional groups that joined as well in 2006.
Q. Why did it disband, GHTF, do you know?
A. I don't have specific reason to offer as to why they disbanded. They did transfer their work over to IMDRF, and it's made up of voluntary membership of regulators, IMDRF.
Q. Is FDA a member of IMDRF?
A. Yes. To my understanding, that's correct.
Q. When did GHTF disband?
A. 2012.
Q. Did IMDRF, to your knowledge, ever make some sort of statement adopting the GHTF guidances?
A. Yes. If you go on the IMDRF website, you will see that they have GHTF archives, and then they have a section where you can have IMDRF documents and GHTF documents. And the GHTF documents and all of those that are included in the binder that we marked as Exhibit 8 are considered current based on that website. If you go on the IMDRF website, you will see archived documents which they will tell you are no longer considered

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current. They are there for reference. They have a list of GHTF documents which are considered current posted on their website.

Q. And the ones that are in your binder and that you have relied on in your reports, are they all under the current part of the IMDRF website?

A. Yes. I went through and verified that each one is listed still on what's considered current by IMDRF.

Q. Now let me ask you about Exhibit 2 of your supplemental report. That is the MAUDE MDR reports. Let me tell you what I think this is and you tell me if I'm right.

As far as I understand it, what you have got listed here in the three different charts are reports that were reported to FDA that you located on the MAUDE database that, in some extent, reference pelvic mesh?

A. Yes. For these particular products and manufacturers, yes.

Q. Did you do the search?

A. It was done under my direction by Christine Swanson, who is one of my staff.

Q. What search terms did she use to come up with the numbers to populate the different columns?

A. I would have to -- I would have to present that to you as a list. For example --

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Q. Did you tell her what to search for?

A. Yes.

Q. Tell me what you told her, essentially.

A. I told her to search from 1999 through the end of 2015 for these particular manufacturers and these product names. And then for Ethicon, for example, where we have combined the sling products, TVT, TVT-O, TVT Obturator, TVT Exact, TVT Abbrevo, TVT Secure. She applied the manufacturer names, the names of the products, and to extract MDR reports that had been submitted to the FDA for those particular products for those particular manufacturers that are listed here.

Q. Now, what was the name of the lady that --

A. Christine Swanson.

Q. What are her qualifications or background?

A. She has a great deal of background as an analyst, a data analyst.

Q. Does she have a master's or something?

A. No.

Q. Tell me if you know her educational background.

A. I don't believe she actually has -- to the best of my recollection as I sit here today, I don't believe she has a bachelor's degree. She has, for example, previously worked at Amgen as an analyst and she has extensive experience in data analytics, data analysis, I

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should say.

Q. I'm trying to follow you there.

Does she not have a college degree?

A. I don't believe she does, not a bachelor's.

Q. She did graduate from high school, though; right?

A. Yes.

Q. How old is she?

A. I don't know specifically. We're not allowed to ask those questions as an employer.

Q. She's not a teenager, is she?

A. No. She has a son that's a teenager.

Q. Did you look at any of the actual reports themselves from the MAUDE database?

A. Yes.

Q. Did you look at all of them?

A. I have not looked at every one, no.

Q. Can you tell me, on the Ethicon sling column, the combined products, there's a total there of 23,083 MDRs, can you tell me how many reports out of those 23,000 plus you actually looked at?

A. I can't give you a specific number, no.

Q. Did you look at a hundred?

A. I certainly looked at more than a hundred, yes.

Q. Of the Ethicon ones?

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A. Yes.

Q. Why did you look at them?

A. Well, I looked at them for a variety of reasons. I have reviewed issue reports in the past as well, and I reviewed MDR reports to look at the information in the MDR reports. First of all, when I give my staff direction, I verify what they're doing and that it's being done correctly. For example, if you look at my Prolift report, which I don't have a copy here --

Q. It's burned in my brain.

A. If you look at my Prolift report, if I'm recalling correctly as I sit here today, you will see there are tabular presentations of particular adverse events that are reported in the MDR database. When I give my staff direction, in order to present, pull out this type of a table, it's a tabulation of numbers of MDR reports that come up for specific search terms. But within the body of the MDR reports, there's a discussion description of the adverse event or events that occurred and were reported in the MDR report. For a tabulation such as those that were presented in my Prolift report, you have to go through and read the MDR report and extract the information that shows there's an erosion or if there's dyspareunia or whatever the adverse event may be.

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Q. Did you do that for this chart?
A. This is a tabulation for all MDR reports. It's not a tabulation of what the specific adverse events were that were reported in those. That information, as you know in the Prolift report, there is that type of information and we did do that for that.
Q. Unfortunately, I can't ask you about that because you have been deposed in the Prolift report.
For this report, Exhibit 2 to your supplement, would I be correct that you don't have it broken out as to what the event is that occurred for, for instance, the Ethicon sling products combined?
A. That's correct. This is a tabulation of the total number of MDR reports for these products, these manufacturers.
Q. Do you have that information stored somewhere else, like at Symbion?
A. For some of them we do where we have gone through and pulled that information out. It takes, obviously, a lot of time to read through each of those and to pull the information out and tabulate it, and we have done that for a number of these.
Q. But not for what I'm now looking at as Exhibit 2?
A. For some of those that information is

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available. Not for all of the MDR reports that are in this tabulation.
Q. And the sum that you're talking about that's available are set out in your previous Prolift reports?
A. And other reports.
Q. And TVT reports?
A. And also the Boston Scientific, for example.
Q. Did you make efforts to call out any duplicate reports?
A. We do try to do that, yes.
Q. Tell me how you try to do that for this exhibit, Exhibit 2.
A. Well, we have done that previously. If it appears --
Q. I want to hear about for this one.
A. If there's definitely a duplicate. For this, I would have to double check exactly how we did it for this particular report.
Q. Do you know, as you sit here today, that efforts were, in fact, taken to call out duplicates from the numbers that are represented in Exhibit 2?
A. To the best of my recollection as I sit here today, yes. Christine always pays attention to try to call out anything that's an obvious duplicate.
Q. Now, did Christine make efforts to call out,

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for instance, if someone had both a TVT and a Prolift implanted and there was one MDR, do you know where she would stick the MDR?
A. Without checking back with her, I would anticipate that it probably would have appeared in both columns.
Q. If I'm looking at the top chart -- and let's just stick with the Ethicon sling column for now -- you can see it jumps from in 2011, there were 270 reports.
Do you see where I am?
A. Yes.
Q. The next year, 2012, there were over 3,000 reports?
A. Correct.
Q. And then the next year, 2013, there were over 16,000 reports; right?
A. Yes.
Q. First of all, let me ask you, for the year where the number was put, is that just the year of the report, when the event was reported?
A. Yes.
Q. So if the event occurred, say, in 2003, but it was reported in 2007, the number goes in 2007?
A. For this chart, yes.
Q. For this chart?

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A. Yes.
Q. Outside a mass litigation like we have here with mesh, have you seen numbers jump to the percentage that you're seeing here, for instance, from 2012 with 3,000 reports to 2013 with 16,000 reports? Have you seen that outside of litigation?
A. Well, I have not looked at it for every product outside of litigation. For those products that I have looked at, I have seen that happen more typically with litigation or if there's some kind of a safety alert or some type of a notification from the FDA that makes people more aware.
Q. Did you make any notations or record of how many of the reports were from litigation?
A. That information is available. I don't have it in this document.
Q. When you say it's available, it's in the MDR report?
A. Right.
Q. Do you all have some kind of work product put together where you have delineated how many of the 16,000 are from litigation?
A. For some of the products we do. For all of the totals here, no, but, for example, I don't have it for AMS. I do have it for some of these products.

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Q. Do you have it for Ethicon products?
A. For some of them, yes.
Q. Which ones?
A. I don't remember specifically without checking back as I sit here today.
Q. When you say you have it for some products, are you saying for all of the TVT reports from '99 to 2015, you may already have that information of how many of those reports were from litigation --
A. Yes.
Q. -- like for TVT?
A. Yes. We have done that analysis for a number of the different products.
Q. Up through 2015?
A. Not completely through 2015 because, if I recall correctly as I sit here today, my prior reports had not gone through 2015, and for this exhibit, updated it through the end of 2015 since we're now into 2016.
Q. The reason I'm asking is, I think you and I had talked before about your previous MAUDE searches, and I did not recall that you had pulled out the ones that were from litigation. That's what I'm trying to help jog your memory if you know which Ethicon devices you have that information for. If you don't, you don't.
A. And maybe calling out, maybe I'm

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misunderstanding the question, so let me clarify. We didn't call out and not include those because that would be inappropriate not to include them.
Q. It would lower the numbers quite a bit, wouldn't it?
A. Yes. It doesn't mean -- just because it's reported in litigation, it doesn't mean they're not real. To not include them would not be an appropriate representation of the data. And what was done here is present an appropriate representation, an accurate representation of the numbers in the MDR reports as possible. Calling out is not the term that I would use. We have done, for some of the products, that analysis where we know how many were reported by attorneys based on the information that's in the MDR report.
Q. Is that in previous reports that you have done on those devices or is that a separate?
A. If I'm recalling correctly, as I sit here today, some of the reports may include the number that were attorney reported, or at least a reference to the fact that some may be attorney reported. I don't recall specifically without looking back at my reports whether or not we gave an actual number, but I know we have done that analysis anticipating, for example, that it would be of interest to you. We have done that analysis for some

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products and that information is certainly available.
Q. Now, I had asked you before as to, for instance, if the patient had been implanted both with an Ethicon sling and an Ethicon Prolift, how the numbers would splice out, and I think you testified, number one, you'd have to check, but number two, you think it might appear in both columns?
A. Yes, I would anticipate it would appear in both columns because, if there was an MDR report for TVT and you don't include it in TVT, then that's an inappropriate representation of the numbers of reports addressing TVT saying for Prolift. It would be most appropriate to include that in both places. If we were doing a more in-depth analysis and we would define -- and we have done these types of analysis before -- we would define how many of those there were.
Q. Did you do that same approach, say, if a patient was implanted with both an Ethicon product and a Boston Scientific product, would the number appear in both columns?
A. Yes.
Q. Did Christine make any attempt at determining whether or not there were some other concomitant causes of the list of adverse events?
A. Not for this tabulation, no.

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Q. You didn't either?
A. Not for this tabulation. This is specifically as it's described a tally of the total numbers of MDR reports that were submitted to FDA for the products of the manufacturers listed here.
Q. Now, for the products listed here for the years, do you have any sort of denominator number? For instance, do you know how many TVT family of slings were sold in 2010?
MR. KUNTZ: I guess I have to object. That's an improper hypothetical. We have asked at least 30 times for that number from you guys and never been given that number. It's an impossibility for her to make the calculation.
BY MS. SUTHERLAND:
Q. You don't have the number?
A. I don't.
MR. KUNTZ: It's impossible. You won't give us that number.
THE WITNESS: No.
MR. KUNTZ: We have been asking for five years, is my point.
BY MS. SUTHERLAND:
Q. With respect to the numbers that are listed in the columns for Ethicon, do you know all of the types of

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events that were listed, such as erosion, pain?
A. Pain, urinary tract problems.
Q. Do you have a listing of what they all were for in the numbers here?
A. I have -- if you go back to the TVT report and my Prolift report, there's an itemization for those specific products for the types of events as well as --
Can you ask the question again?
Q. Sure.
For this exhibit that you put together for the supplemental report, do you have a listing of the events that are included?
A. For some of the products, yes, but this is -- again, I reiterate, this is a tally of all of the MDR reports that were submitted for those products. For some of these products and for certain of the years, we have done a tabulation of the numbers of erosions that were reported, the numbers of pain that were reported, the numbers of dyspareunia that were reported, the number of urinary tract issues that were reported, the number of infections that were reported. And our numbers are consistent with FDA's representation of what they reported they found in the MAUDE database, for example, in their 2008 public health notification and their update in 2011, their safety communication. And, in fact, I

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state that in my reports where we have presented that type of information at that level of detail, that what we found for the specific products were representative of what FDA found across the numbers of manufacturers that FDA evaluated and published, for example, in its 2011 review of the MAUDE database and the literature relevant to transvaginal meshes, particularly, pelvic organ prolapse for the discussion here today.
Q. How long has Christine Swanson worked for you?
A. Over a year, at this point, if I recall correctly.
MS. SUTHERLAND: I'll hand you and attach the supplemental report for TVT.
(Defendant's Exhibit 4 was marked for identification by the court reporter.)
BY MS. SUTHERLAND:
Q. Is that your supplemental report on TVT and TVT-O dated March 2016?
A. Yes, March 2, 2016.
MS. SUTHERLAND: You can set that aside. I think we're on the same page, that with the Ramirez depo coming up in a couple of weeks, that I'll address that then.
MR. KUNTZ: Yes. Are you doing the depo?
MS. SUTHERLAND: Unless I can get out of it.

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MR. KUNTZ: It will help.
MS. SUTHERLAND: Yes. If someone else covers it, I will definitely make sure it's squared away on what we agreed to.
MR. KUNTZ: For the record, I'll have them file that in Ramirez too, if need be.
MS. SUTHERLAND: If need be.
BY MS. SUTHERLAND:
Q. Now, let's go back to your February Prosima report.
Do you need a break or anything? We have been going over an hour.
A. I wouldn't mind.
MS. SUTHERLAND: Let's go off the record.
(Recess.)
BY MS. SUTHERLAND:
Q. Quickly, Pence Exhibit 2 to your Prosima February report is your CV.
Is that pretty much up to date?
A. Yes and no. I was looking at this the other day that I need to update the address, so the address.
Q. You still have Newbury Park?
A. Exactly. We do have the satellite office, basically, with my staff working remotely, but that old address is no longer accurate. I do need to update that.

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There are a couple things to add to it. What's here is correct.
Q. What are you adding to it? Presentations?
A. Not presentations so much as conferences that I have attended, continuing education in my profession. There are old publications that I located to be added that I had forgotten about that I have not added.
Q. Do any of those old publications have to do with pelvic mesh?
A. No.
Q. Do they have to do with an implanted device?
A. Not to my recollection.
Q. Any of the conferences that you have attended that aren't in your CV, did any of those conferences have anything to do with pelvic mesh?
A. No.
Q. Now, Exhibit 3 to your Prosima report is your reliance list, and I wanted to make sure on this, and Jeff, you might want to listen to this one part.
MR. KUNTZ: I'm listening.
THE WITNESS: Go ahead.
BY MS. SUTHERLAND:
Q. I didn't get any reliance lists with the supplemental reports, and I wanted to make sure that I was not supposed to get any updated reliance list with

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the supplemental reports in March.
Do you know, Dr. Pence, and then I can talk to Jeff off the record?
A. I have the information footnoted in my supplemental report. I didn't provide a reliance list additional to that.
Q. I just wanted to make sure I didn't miss it if you had it.
A. It's either referenced or footnoted in my report that I relied on for inclusion in the supplemental report.
MR. KUNTZ: Let's off the record real quick.
MS. SUTHERLAND: Okay.
(Recess.)
MS. SUTHERLAND: Now we're back on.
BY MS. SUTHERLAND:
Q. Dr. Pence, you were telling me about your CV.
A. Yes. Looking at Exhibit 2, which is my CV, it looks as though this one is not the most updated version, unless I am overlooking it. Like, for example, the selected presentations, October 1, 2013, and selected continuing education, 2013 is the last listed there. And I note that in particular because you asked me about presentations, and for example, I did chair a session at the annual FDA Orange County Regulatory Affairs, OCRA

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discussion group meeting last year, that would have been 2015, and I also, if I recall correctly, 2014. I think this is an older copy.
Q. You think you have one that's updated?
A. Yes. This is an older copy that was produced, it appears.
Q. I'm sure I'll follow up with a request to Jeff to get the updated CV, and if you want to update the address and anything else that you saw, do that for me, please.
A. I will do that.
Q. Exhibit 5 is a listing of RCTs on prolapse repair; correct?
A. Yes.
Q. It says at the top, "Randomized controlled clinical trials."
Did you pull this from a different report?
A. Yes, and that didn't get corrected.
Q. Do you know what report you might have pulled Exhibit 5 from?
A. Yes.
Q. I'm assuming it was Prolift?
A. No. Actually, the Prolift report, if I recall correctly, only had five summarized, and in one of my BSC reports, I updated that to include all of those here.

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There was -- the Exhibit 2, I apologize, didn't get changed.
Q. No worries. That actually helped me out because I had thought that I already asked you about this document. Apparently I have not if this was Boston Scientific.
A. Some of them you had at one point asked me about part of these.
Q. Just tell me real quickly, these are not all of the RCTs on prolapse repair, are they?
A. No.
Q. How did you --
A. Not to my recollection. These were some of the key ones I identified, and I believe it's stated in my report, between 2008 and 2012.
Q. When you say they're one of the key ones, were they of a certain strength or length? If you can, tell me why you denoted them as key.
A. When I originally did this, it was back in 2014. At this point in time, as I sit here today, I can't recall exactly why I chose these particular ones, except that, of course, they were randomized controlled trials and that, obviously, that's the highest level of evidence. Depending on the quality, it's generally considered the highest level of evidence, but you have to

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evaluate each study individually. And because these were randomized controlled clinical trials with and without mesh, the "with and without mesh" was, of course, important to my consideration of including those in here.
Q. Just so I'm clear, I don't know if I asked it this way: Are there other randomized controlled trials that are published and available with and without mesh that are not included in your Exhibit 5 or did you get them all?
A. No. Yes, there are.
Q. There are other additional RCTs out there on mesh and non-mesh doing a head-to-head comparison?
A. Yes.
Q. As you sit here today -- I know you did this a while back -- you can't tell me why you picked out these particular studies that are in here?
A. I don't recall every reason that I picked those out except for what I just mentioned, because it was back in 2014, but clearly, they were randomized controlled trials, which is a high level of evidence. They were a comparison to without mesh. They were articles that I found referenced in a number of other articles, and so I thought they were representative. That would have been the standard, that they are representative of the literature at that time from 2008 to 2012.

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Q. As you sit here today, do you have any plans to supplement your Prosima or Prolift reports, just as you sit here today?
A. As I sit here today, I don't have specific plans to supplement my report, but I reserve the right to supplement the report if needed.
Q. Have you read any of the defense expert records from Wave 1 in the MDL?
A. Perhaps you can clarify who those were because I don't know specifically. I have read, obviously, defense expert reports over the period of the last couple of years.
Q. Let me ask it this way: Have you read any defense expert reports in the past month that were dated within the past month?
MR. KUNTZ: Past week.
BY MS. SUTHERLAND:
Q. Past week?
A. No.
Q. Now, I caught myself reading your report and your exhibits. I did not see a list of testimony for the past four years.
Do you have a list of testimony, both deposition and trial?
A. Yes.

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Q. You don't mind getting that to Jeff?
A. No.
Q. Along with your updated CV?
A. No. In fact, I did produce that when we were -- for the February 1st Prosima report, but it wasn't provided to you then?
Q. I did not see that. Was it written within your report?
A. No.
Q. I caught myself reading it.
A. It was typed.
Q. It wasn't attached to what I have seen, and I only saw the five exhibits.
A. I don't include it in my report, but I did provide it to Counsel.
Q. That's not a problem. We'll get it.
I did not see in your report where you listed what your hourly rate is.
Can you tell me what that is?
A. Yes. It's $500 an hour.
Q. And is that both for testimony and review of documents?
A. Yes.
Q. For your Prosima report and your supplemental reports, both Prosima, Prolift, and your TVT supplemental

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reports, do you know how many hours you have billed on that work?
A. Repeat that again. I'm sorry.
Q. What I'm trying to limit it to is the recent work you have done on Ethicon products, and as far as I know, that would be your Prosima report, your supplemental Prosima and Prolift report, and your supplemental TVT report.
Do you know approximately how many hours you put into that work?
A. I can tell you for the Prosima report, the February 1st, 2016, Prosima report, that I have an invoice ready to be submitted that's a little over $34,000. I spent approximately 67 hours and Christine has over 13 hours, between 13 and 14 hours, to the best of my recollection as I sit here today. I have not totaled my time yet over the last couple of weeks for the supplemental report for TVT and Prosima and preparation for the deposition.
Q. Do you have a ballpark of what you think that might be?
A. As I say, I haven't totaled it. If you're including TVT, it's probably somewhere 60 to 100 hours. Without totaling it, that's my best estimate as I sit here today.

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Q. Am I correct that you're not offering a manufacturing defect opinion for any Ethicon device?
A. Can you clarify?
Q. Yes. For any particular lot or batch that went through, that something went wrong in the manufacturing process. Are you offering any opinion like that for any Ethicon device?
A. If you're asking me for a specific batch and manufacturing processing, as I sit here today, it's my understanding I won't be asked to offer those kinds of opinions. If you're talking about information with regard to mesh characteristics --
Q. No, I'm not. I'm talking literally as it's going through the warehouse and something went wrong on the worktable going through the factory.
A. That specific kind of information I have not been asked to opine on at this point in time.
Q. I didn't have page numbers on your Prosima report.
A. There aren't.
Q. So if you'll flip over to about page 18, and what I'm looking under is, "Prosima Development Challenges and Failures."
As I understand it, you have five opinions for Prosima set out in your report; correct?

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A. Yes.
Q. Now, obviously, you and I have talked about Prosima before?
A. Yes.
Q. So I'm limiting my questioning to what I have not asked you about before, at least to the best of my recollection and my review of the Cavness stip, which I will confess is quick.
One thing I want to ask you about under 18, "Carey, Slack, Clinical Evaluation of Prosima Prototype," if you're with me. Underneath there, you note, "The disclosure of certain financial interests is the standard or required practice for clinical investigators when submitting clinical study reports for publication."
A. Yes.
Q. Now, if I'm reading that correctly, you were not saying that this is some standard that Ethicon breached with respect to disclosure of financial interests, or are you? Maybe I should ask it that way.
A. I think the answer to that is both, both the authors as well as Ethicon, because --
Q. That answers the question. Let me ask the next question.
Can you tell me where the standard is written that you're saying Ethicon breached with some failure to

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disclose financial interest?
A. Yes. Publications, generally, expect any disclosure of financial or proprietary interest to be disclosed. The FDA 21 CFR Part 54 on financial disclosures, an FDA regulation -- and give me just a moment.
Q. Are you looking for the standard?
A. Yes.
Q. Are you thinking it's something besides the FDA standard that we talked about?
A. Yes. To the best of my recollection, disclosure of proprietary and financial interest is also included in international standards, whether it's GHTF or ISO, to the best of my recollection as I sit here today.
Q. You didn't cite any ISO standards in any of your Prosima reports that I saw, did you?
A. No. If you look at the GHTF documents, a number of them do have, in the reference documents, ISO standards.
Q. Do you know which GHTF document you're talking about that might have the standard to disclose financial interest?
A. Not to the best of my recollection sitting here today. I would have to double check that.
Q. The disclosure that you're talking about, are

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you talking about just making a disclosure to the publication that was going to publish Dr. Carey's results?
A. Well, also, it was not the financial interest. There was a poster presentation that was included. And now we're talking about FDA, but there was --
Q. I'll go ahead and tell you, I really don't want to talk about FDA today, which I know surprises you and me both, but I want to focus on standards other than FDA for today.
A. That's fine. Yes, there was no disclosure in the publication and, therefore, it's a matter of people reviewing, any reader reviewing an article, being able to judge the information in the article in consideration of any potential bias by virtue of one of the investigator's or more than one investigators' financial interest in a product that is being reviewed. That's the whole reason for disclosure, so that that information can be taken into account by the reviewer.
Q. With publications, that information is generally provided by the investigator; correct?
A. That is correct. However, Ethicon was very heavily involved in the development of this information. In fact, you will note that on page 20 in the report -- I realize there are no page numbers there -- but page 20,

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that Dr. Robinson noted that BJOG had agreed to publish Carey's study, but that it would require a major rewrite. And Dr. Robinson, reflecting on the internal team's concerns about the large number of patients lost to follow up, and that Dr. Carey had submitted the draft manuscript without Ethicon's review, remarked, "This seems the best of both worlds. We get the chance to revise the data, Marcus's wishes to work with the clinical team here in developing the manuscript, and we have the agreement from the journal that they will publish once they are happy with the manuscript." Ethicon definitely had involvement.
Q. I want to be sure that I know the extent of your opinion. Is the financial disclosure that you're talking about something that should have been made to BJOG?
A. Yes.
Q. If I'm reading your report correctly --
A. If we're excluding FDA for this discussion. It should have been made to FDA with the poster presentation presented to FDA. If we're excluding FDA, then yes.
Q. Now, the disclosure that we're talking about that should have been made to BJOG was the amount paid to Dr. Carey?
A. It should have been that he had a financial

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interest, a consulting relationship, and that the product had been licensed, that he had a proprietary interest in the development of the product.

Q. It's your understanding that was not done?

A. Correct. I did not find that the published paper included any disclosure of his financial interest or Ethicon's involvement.

Q. Do you know if that information was provided to BJOG otherwise? You know, the publication sends their conflict of interest document that goes with the publication itself. Do you know if disclosure was made to BJOG but was not included in the published report?

A. As I sit here today, I don't recall having seen that.

Q. Let me turn over to your first opinion that's listed in the report, which is on page 32. I'm going to try to cut through this.

As I understand it, this opinion focuses on what -- your opinion was not provided to FDA, and had FDA known certain things, it would not have cleared Prosima.

Is that a fair nutshell?

A. As I understand your question, yes.

Q. Let's go to Opinion 2, which is, as I understand it -- let me ask you this: For Opinion 2, if I'm understanding, is it your opinion that there were

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inadequate studies, clinical studies, to support the marketing of Prosima? Is that part of your Opinion 2?

A. That is part of my Opinion 2, yes.

Q. Is the second half of your Opinion 2 that after Prosima was marketed, there remained a lack of clinical studies showing its safety and efficacy? And I'll tell you what I'm trying to do here is have a dividing line between premarket and postmarket if we can do that with your opinion.

A. Give me one moment. Can you repeat your question, please?

Q. Yes, ma'am.

If I'm understanding your Opinion 2 correctly, does it cover both premarket studies, which, in your opinion, did not show safety and efficacy of Prosima, and postmarket studies, which did not show safety and efficacy of Prosima?

A. Yes.

Q. So let me try to address those in two separate buckets, if I could, just to keep things clear. You and I have already talked about the studies that were conducted back in Cavness. Really, what I'm focusing on here are the standards that you're relying on for your opinions.

The first question I want to ask you is, about

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two-thirds of the way down in that paragraph, you say, "There Ethicon failed to follow the requirement it created for releasing the Prosima onto the market. If Ethicon had followed its own internal requirement related to safety and performance of the Prosima, it never would have been released."

A. Right.

Q. The question to you is: What internal requirement of Ethicon are we talking about there, just so I know?

A. It was the project charter, and it is referenced in my report. Let me just locate it. It's on page 18 of the report, at the very end of the paragraph at the top of the page, "Importantly at the outset of the Project Mint charter."

Q. I'm not with you yet. I think I'm on 18.

A. Middle of the page, it has Section B, "Prosima development challenges and failures." At the top of that page, the last sentence of that paragraph, "Importantly at the outset of the Project Mint charter," which was Prosima, for Prosima, what became Prosima, I should say, "Ethicon recognized that if the results of the clinical evaluation performed by the inventor, Dr. Marcus Carey, and his development partner, Dr. Mark Slack of Cambridge, United Kingdom, were not favorable, the project should be

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abandoned or the scope changed."

Q. And you reference there Footnote 40?

A. Yes.

Q. Is Footnote 40 the document that supports that sentence?

A. Yes, Project Mint charter presentation from June of 2005.

Q. We go on -- and I'm back at page 33 -- "For all medical devices, the internationally accepted standard of care is that a clinical evaluation of the device, including clinical data, show a favorable benefit-risk ratio."

A. Correct.

Q. Now, where is that internationally accepted standard of care written?

A. It's repeated in a variety of documents, but if you look at Exhibit 1 in the supplemental report and you go to the essential principles of safety and performance, for example, to page 3 in that Exhibit 1 of the supplemental report, one of the principles in essential principles of safety and performance -- let me start on the prior page, on page 2, with the very first essential principle of safety and performance that's listed. "Medical devices should be designed and manufactured in such a way that, when used under the conditions and for

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the purposes intended and where applicable, by virtue of the technical knowledge, experience, education or training, and the medical and physical conditions of intended users, they will perform as intended by the manufacturer and not compromise the clinical condition or the safety of patients, provided that any risk which may be associated with their use constitute acceptable risk when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety."

Q. Where does that come from?

A. This comes from the final document, Global Harmonization Task Force, Essential Principles of Safety and Performance of Medical Devices.

Q. That's what I'm going to hand you, Exhibit 10.

(Defendant's Exhibit 10 was marked for identification by the court reporter.)

BY MS. SUTHERLAND:

Q. Is that a document that sets out the standard that you reference back in your report on page 33? What I want to do is I want to get what all of the standards are. If I have questions about those, I'll come back.

A. Repeat the last question.

Q. Yes, ma'am.

I'm back on page 33. What I'd asked you there

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was, you reference an internationally accepted standard of care in that bottom part of that paragraph.

A. Yes.

Q. My question to you is: Is that internationally accepted standard of care that you're referencing contained in what I have now marked as Deposition Exhibit Number 10?

A. It is contained in here, and also, the risk-benefit information is also. The need for favorable benefit-risk assessment for marketing of a medical device is also referenced in other standards, other GHTF standards.

Q. What are those?

A. For example, the --

Q. Put a pin in that and we'll come back to that.

For the sentence that you have got written here on page 33 which talks about, "For all medical devices, the internationally accepted standard of care is that a clinical evaluation of the device, including clinical data in the form of clinical studies, literature, clinical experience, must demonstrate that a favorable benefit-risk ratio exists for the device."

For that sentence, you're saying you look to that standard which is contained in GHTF, Essential Principles of Safety and Performance of Medical Devices,

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which I have marked as Number 10; correct?

A. Yes.

Q. And then you said there are other GHTF guidance documents that also have that same standard?

A. Well, they reference back to the essential principles of safety and performance, which include a favorable benefit risk. For example, if you go to the clinical evaluation, May 2007.

Q. You got to slow down. I want to get them all. Tell what that was, May 2007 clinical evaluation?

A. May 2007, yes.

MS. SUTHERLAND: I'll mark that as Number 11. I am not going to have all of these. I tried to get all of them that I could.

(Defendant's Exhibit 11 was marked for identification by the court reporter.)

BY MS. SUTHERLAND:

Q. I'm handing you what I marked as Number 11.

Is that the second standard that you were just discussing?

A. Yes.

Q. Now, is there another one?

A. For example, in the document -- this is the point I'm trying to make -- the GHTF documents represent a global model that has been accepted internationally for

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the development of medical devices. For example, if you start with the essential principles of safety and performance, if you look at the clinical evaluation document, Exhibit 11, if you look on page 6, you'll see, under the references, that this document references the essential principles of safety and performance of medical devices. Now, Exhibit 10 happens to be the 2012 update to a 2005 document on essential principles of safety and performance. So you'll see, because the clinical evaluation document was May of 2007, that the essential principles of safety and performance document that it references was the 2005 document.

There were updates to these documents over the period of the 20 years of the existence of the GHTF, but there's an interrelationship between these documents that support one another in creating this model for a global clinical development. These various standards support the efforts that need to be undertaken to demonstrate conformity to the essential principles of safety and performance.

So you'll see in this clinical evaluation, Exhibit 11, that one of the documents it references is also the principles of conformity assessment for medical devices, which is another standard, and that that standard also references back to the essential principles

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of safety and performance.
Q. Did you go back and review the 2005 essential principles?
A. Yes, I certainly have.
Q. Did you do that for your opinion in this case?
A. To the best of my recollection, I did, yes.
Q. Do you know what the differences are between the 2005 version and the 2012 version?
A. If I recall correctly, if I'm not confusing the standards, one of the key differences was the inclusion of information relative to in vitro diagnostic devices.
Q. I'm asking you that based on your phrasing here on page 33 where you say, "For all medical devices, the internationally accepted standard of care is that a clinical evaluation of the device includes clinical data in the form of clinical studies."
My question to you is: Is it your opinion that all medical devices require clinical data in order to have an analysis of the benefit-risk ratio?
A. I think I need clarification. Can you point me again to the statement you're referencing?
Q. Down on page 33, the sentence we have been talking about, where it says, "For all medical devices." It starts over on the left-hand side.
A. I have it.

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Q. That's the sentence I'm focusing on.
A. Yes.
Q. My question is, if I'm reading that sentence, it reads to me that your opinion is that all medical devices require clinical data, meaning in human use, to have an analysis of the benefit-risk ratio.
Is that your opinion?
A. That's what's stated in the standard, but clinical data can be in the form of scientific medical literature and commercial experience as well as clinical studies.
Q. So for a new device that's coming out where you don't have published medical literature yet and you don't have previous clinical experience because it's a new device, am I understanding your opinion to be that the standard that you're referencing from GHTF is that you have to have a clinical trial in order to analyze that benefit-risk ratio?
A. No, that's not what the standard says. In analyzing the benefit-to-risk ratio, because we're talking for Class II devices --
Q. Correct, at least at the time.
A. We were talking about Class II devices, and then, of course, Class III devices now that they have been reclassified to high risk, but for medium risk

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devices, because we're talking about devices that have been marketed based on similarity to previously marketed devices, the standard allows you to evaluate the literature for similar devices or commercial experience. Hence, that goes to why I looked at the MDR database because that's publicly available information that a manufacturer can look at for competitor products that are similar to look at the clinical experience.
If looking at that totality of information that is available, one can rely on that based on comparing one's own device to the other devices that are represented in that, when we're talking about a brand-new device. If the manufacturer can substantiate, based on that available information, that there's a favorable benefit-risk ratio, then premarket clinical studies may not be required. Based on distinctions between your device and similar devices --
Q. I think you answered the question.
A. -- then clinical studies may be required. As I have testified to before -- I just need to answer this to be complete --
Q. It sounded pretty complete.
A. -- then the company has to make a determination that they may need to do clinical studies in order to show that there's a favorable benefit-to-risk ratio.

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Q. I think I can get this as a yes or no.
Am I correct, Dr. Pence, that the GHTF standards that you and I have talked about don't set out a bright-line rule saying for all medical devices, you have to have clinical data, meaning trials in humans, before you may analyze the benefit-to-risk ratio?
MR. KUNTZ: Objection to form.
THE WITNESS: As you stated that, I can't give you yes or no because the clinical data includes -- doesn't include just clinical investigations on a specific device.
BY MS. SUTHERLAND:
Q. For my purposes for this question, when I'm talking about clinical data, I'm talking about the company that has the device that they want to market running a clinical trial in humans.
A. If you're talking about running a clinical trial in humans specifically, if -- again, it's very qualified. One has to do this on an individual device basis to decide whether or not your device -- if other devices for which there is data or which there are data, either in terms of commercial experience and literature, if those data are adequate to substantiate a favorable benefit-risk ratio for your device, considering the differences of your device to those devices on which

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information is available, if you can substantiate a favorable benefit-risk ratio based on such evidence, then you would not have to do clinical trials. But if you can't, then you need to do clinical studies to demonstrate a favorable benefit-risk ratio.

Q. So no bright-line rule from the GHTF documents saying you always have to run a clinical trial before you can sell a device?

A. It's a case-by-case basis depending on the differences in the device and whether the information that is already available for other devices or maybe a prior device, and your device is a modification of the prior device, whether the information is --

Q. It really is yes or no.

There's no bright-line rule from the GHTF documents you and I have talked about saying you always have to run a clinical trial in humans before you can evaluate the benefit-risk ratio, yes or no?

MR. KUNTZ: Objection. Asked and answered.

THE WITNESS: For the reasons I have mentioned you have to evaluate, no, you have to evaluate on an individual basis, case by case.

BY MS. SUTHERLAND:

Q. I think we got our yeses and nos mixed up there. Let me try one last time.

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There is no bright-line rule in the GHTF documents that you and I have talked about saying that a manufacturer always has to run clinical trials in humans before that manufacturer can adequately assess the benefit-risk-ratio; right?

A. As I understand your question, right, there is no bright-line rule because every product is different, but the bright-line rule is that you must be able to demonstrate a favorable benefit-risk ratio on available evidence.

Q. You answered my question. I got it.

Is there a standard that a manufacturer can go to to tell them, if they think they need to run a clinical trial, how to set it up: How many people need to be in it, how long does it need to be, what end points? Is there some written standard that a manufacturer can go to that sets that out for them?

A. That sets out the foundation, yes. One is the GHTF clinical investigations.

Q. What standard is that, clinical investigations?

A. It's in Exhibit 8 under the tab, "Clinical investigations." The title of the document is, "Clinical Investigations," authored by Study Group 5 of the Global Harmonization Task Force, February 12th, 2010.

Q. For instance, let me give you an example of

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what I'm looking for. Does that standard set out the size of the clinical trial a manufacturer would have to do?

A. That's based on statistics. It gives you the principles, and it gives additional references as well, but it gives you the principles for doing a clinical investigation, and it also references other international standards. I mentioned ISO standards and GHTF standards, also referenced ISO standards, and in this document, for example, on page 5, it references ISO 14155-1 and ISO 14155-2, both 2003 documents.

Q. Do those set out the size? Is there something seriously a manufacturer can look at that says I need 50 people? 150 people?

A. That's based on statistics. When you're designing a clinical trial, the standards say you set out your end points, your objectives. And when you're designing a clinical trial, you make a decision as to what kind of a different -- if you're doing a comparison.

Q. Is it a case-by-case decision, essentially?

A. Yes, it is, based on what your end point is going to be, and then the statistician determines how many patients need to be included in each arm.

Q. Is it also a case-by-case decision as to how long you need your study to go?

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A. Yes. It depends on the medical device. If you're doing an ocular treatment that's an eye drop, you don't need to follow those patients for their lifetime, for example. If you're doing a permanent implant and a registry study, for example, you would want to follow them as long as possible so you have long-term data. It's very dependent on the product.

Q. For a permanent implant that a manufacturer would like to get marketed before the passage of a generation of people, is there some sort of standard that sets out how long a clinical trial would need to go to adequately assess the benefit-risk ratio?

A. There are authoritative bodies that have provided that information with regard to permanent implants.

Q. Is that a standard I can look at? You're turning to the supplemental report?

A. I am.

Q. Exhibit 1?

A. Yes. I do talk about implantable devices more in the context of labeling in Exhibit 1.

Can you repeat the question?

Q. Yes, ma'am. I was wondering is there a standard that sets out a general length of time that a manufacturer who is making a permanent implant would need

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to have follow-up before they can make an analysis of the benefit-risk ratio before marketing? Is there a standard that sets that out for a permanent implant?
A. As I sit here today, I don't recall having seen a standard that specifically sets out prior to marketing. Again, it depends on a favorable benefit-risk ratio. It depends on whether alternative treatments are available. It's the kind of information that, prior to marketing, a company works out with the regulators. If you look --
Q. I think you answered my question.
A. I just want to be complete. If you look at what's -- at minimum a year for short term. If you look at what authoritative bodies are looking at for medium term or long term, it's three to five for medium term and beyond five years for long term.
Q. Is that FDA that you're talking about that refers to medium term as three to five years and long term as five years or more?
A. It's not just FDA. It's some of the other authoritative bodies that have looked at information. For example, I believe it's -- I want to say it's NICE, but I have to double check my memory --
Q. I think you answered the question.
A. -- that talks about medium is five years and long term is ten years. But it's information that a

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manufacturer works out with the body that's going to give it authorization to market the product --
Q. And here in the U.S., that would be the FDA?
A. That would be the FDA here in the U.S.
-- and then makes a commitment, if that authoritative body that provides authorization for marketing allows them to market on one-year data or two-year data, and that's going to also be dependent on what the results are for that period of time.
Q. I think you answered the question.
A. But it will be with the commitment to continue following patients for a certain period of time based on working that out with the authoritative body that provides authorization for marketing.
Q. When was Prosima put on the market?
A. Various documentation, if I recall correctly, shows around December of 2009, some show 2010, but in that time frame.
Q. Now, are you intending to opine to a jury -- let me address this just with Prosima first off. Are you intending to opine to a jury that a specific clinical trial should have been conducted on Prosima before it was marketed?
A. Yes.
Q. You have answered my question.

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A. Yes.
Q. With respect to --
A. If asked, I will.
Q. If asked, you will.
With respect to that opinion, do you intend to offer an opinion as to how many women should have been enrolled in that study?
A. Not a specific number of women, no, because I would need to involve a statistician to write out the protocol and the end points.
Q. That would be a no?
A. I'd need to provide that to a statistician to give me the numbers that we needed to demonstrate the safety and efficacy end points that we've set out as objectives in the protocol.
Q. The question was, do you intend to offer an opinion as to the number of women that should have been in a clinical trial for Prosima prelaunch, I think the answer was no?
A. The answer would be an adequate number to demonstrate safety and performance as outlined in the protocol.
Q. Do you have a number that you intend to offer to a jury that should have been in some clinical trial before launch?

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A. Without designing the protocol and doing the appropriate statistics to come up with the right number to demonstrate safety and effectiveness based on the end points of the trial, I can't give you a specific number.
Q. You haven't drafted a protocol to that end, have you, for Prosima?
A. No, I have not.
Q. Do you intend to, as you sit here today?
A. If I were asked to do that, I would. I have not been asked to do that at this point in time.
Q. Having not been asked to do that, you don't intend to do that right now out of the goodness of your heart, do you?
A. That's currently not my plan, as I sit here today.
Q. I have maybe 15 more minutes, so let me get to another opinion. If we can turn to your opinion on labeling. Go back to your full Prosima report. I'm on page 41 and 42, do you see that, Opinion 3 and 4.
The first thing I want to do is what I did before. For your opinion in Number 3 with respect to looking at that first paragraph. And underneath there, about halfway down the first paragraph, you say, "The globally recognized industry standard for prescription devices, such as Prosima, is for the product IFU to

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contain information necessary," and you go on.
A. Yes.
Q. Now, that Footnote 146 references the GHTF label and instructions for use document; correct?
A. Correct.
Q. You wrote that it supersedes previous version in June 2005?
A. Yes.
Q. Now, is that document that's referenced in 146 where the globally recognized industry standard is set out that you reference here in Opinion 3?
A. Yes.
MS. SUTHERLAND: Let me unload another document. I'm going to hand you what I have marked as Number 12.
(Defendant's Exhibit 12 was marked for identification by the court reporter.)
BY MS. SUTHERLAND:
Q. Am I handing you as Number 12 the documents referenced in Footnote 146?
A. Yes.
Q. Now, other than what I have just handed you, the GHTF document from 2011 (superseding 2005) is there another document that you're referring to there that sets out any kind of labeling standard on which you rely on

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for your opinion?
MR. KUNTZ: I'm going to object. It's vague.
BY MS. SUTHERLAND:
Q. I can rephrase if you didn't understand.
MR. KUNTZ: Related to just the GHTF or all documents?
BY MS. SUTHERLAND:
Q. My question was a document that sets out the standard in addition to what we have already marked, is there another document that I can look at that sets out the standard for labeling for which you're relying on for your opinion contained in Number 3?
A. I want to look up something for a moment, but I want to say that the initial labeling for medical devices standard that predated the 2011 and the 2005 was in February of 2000, and it is included in the binder of GHTF final documents.
Q. Was that the first one?
A. To the best of my recollection. That's to the best of my recollection, yes.
Q. TVT came out before that, didn't it?
A. Yes, it did. I'm just trying to think back. When I told you about current documents, I did include in the binder GHTF documents, some of the predate documents, and I'd have to double check whether the 2000 is still

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listed. That's obviously been updated. I wanted you to know that there were prior standards that didn't just happen in 2011 and 2005. I did include that.
Q. Are you telling me that, to some extent, because you read Judge Goodwin's order on the relevancy of documents that came out after a device had been marketed?
A. I'm telling you that because any time documents are predated by other documents, one has to incorporate by reference those prior documents.
Q. Does it not have anything to do with Judge Goodwin's order?
A. I did see that in the order, yes, but my typical practice is to be comprehensive. And you'll notice that in prior documents that I have referenced SOP documents that were superseded prior to ever reading that.
With regard to the rest of the question about is this the sole document I rely on, again, as I described earlier, the interrelationship between these documents. And for example, if you look at Exhibit 10, "The Essential Principles of Safety and Performance of Medical Devices," and you look at the table of contents, B 13 under Section 7 is label and instructions for use. These documents, as I mentioned, are interrelated. If

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you look at the reference page in that Exhibit 10 on essential principles of safety and performance, you'll see that one of the reference documents is the label and instructions for use for medical devices.
Additionally, if you look in what's Exhibit 8, the second tab, the guidance document, principles of conformity assessment for medical devices, you will see that in the documents referenced there, the label instructions for use for medical devices is included.
Again, if you look under the third tab also in Exhibit 8, the summary technical documentation for demonstrating conformity to the essential principles of safety and conformance of medical devices (STED), you will see, also, that -- in this case, it references the 2005 document, labeling for medical devices is referenced.
Q. Multiple documents is what you're telling me?
A. Multiple documents, yes.
Q. Let me ask you this: You and I have talked before about the blue book memo from 1991; right?
A. Yes.
Q. And as I understand it, that sets out a standard that you warn of risks that are associated with the device; correct?
A. Yes.

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Q. Now, is there a similar standard setting out what risks you need to warn about in those GHTF documents that you told me?
A. Yes, and it's stated in my report. If you look at Exhibit 1 to the supplemental report, at the bottom of page 5, there's a discussion on labeling.
If you see at the top of page 6, the standard is that instructions for use should include any residual risk. And importantly, risk is defined as the probability of occurrence of the risk -- a combination of the probability of occurrence of the risk and the severity of the risk. Instructions for use should include any residual risk, warnings, precautions, limitations, or contraindications and measures to be taken. The information included in the instructions for use should be consistent with available clinical data, and all the hazards -- emphasis on all -- all the hazards and other clinically relevant information should be identified appropriately. Any expected and foreseeable side effects, including information to be provided to the patient, should be included in the instructions for use, and any residual risk identified in a risk analysis should be reflected as contraindications or warnings within the labeling.
Q. Now, would you agree with me that -- you have

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risks associated with just surgery itself, and then you have risks associated with the use of the device.
Are you following me?
A. Yes.
Q. Turn to page 35 and 36 of your original Prosima report.
A. Yes.
Q. Yours looks different than mine.
A. I'm sorry.
Q. I know we're talking about prolapse in this instance, and you have a list of risks under adverse reactions.
Do you see that?
A. Yes.
Q. And it starts with hematoma and goes through procedure failure.
A. Yes.
MS. SUTHERLAND: Can we go off for a minute?
(Recess.)
BY MS. SUTHERLAND:
Q. We were looking at the risks you have listed under adverse reactions from hematoma to procedure failure; correct?
A. Yes.
Q. Now, you understand that there are ways, other

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than with mesh, to correct prolapse; correct?
A. Yes.
Q. Surgeries, other than with mesh; right?
A. Yes.
Q. Now, are you familiar enough with those other surgeries to tell me which of the risks listed here in this first section, from hematoma to procedure failure, you do not have if you don't use mesh?
A. That you do not have?
Q. Right. Are there any risks there listed that you don't have if you don't use mesh?
A. Contracture of the mesh itself.
Q. Any other ones that you do not have if you don't use mesh?
MR. KUNTZ: I'm going to object as vague as to postoperative or long-term.
THE WITNESS: In fact, I was just going to say what you have to consider here is not only -- I have pointed that out in multiple reports, not only whether or not they occur with other procedures, but the difference in the frequency of occurrence and the severity of occurrence, the permanency of the occurrence.
BY MS. SUTHERLAND:
Q. I'll get to that. Right now the only question is -- and I think you answered that -- just out of the

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first grouping, from hematoma to procedure failure, are there risks there that you don't have if you don't use mesh? And you told me contracture, which you equated to contracture of mesh; correct?
A. Yes. I would also add, although pain is listed here -- you have to define what the list is, and it's defined in my report that these were, this particular list, is a list of adverse events that Ethicon had been requested, in this case by FDA, to add to the Prolift.
Q. That's not what I asked you. I didn't ask you anything about that.
A. We're talking about a specific list.
Q. There's no question pending.
A. I'm still answering the prior question. You asked me if these were all -- if that was the only one.
Pain is listed here because that's how it was presented by FDA, but chronic pain is not listed here, and chronic pain is something, for example, that you find with mesh and typically not with other procedures.
Q. Do you have chronic pain at all with other procedures to fix prolapse when you don't use mesh?
MR. KUNTZ: Objection.
BY MS. SUTHERLAND:
Q. Have you seen that in the literature?
A. Not in the same fashion.

Q. Have you seen it in the literature?
A. To the best of my recollection, it may be a possibility, but not to the extent or the severity or the life-altering way that you see with mesh.
Q. The question to wrap up -- assuming, when we come back March 24th, I think I can figure the rest of this out through the TVT aspect.
My question to wrap up here before I race to my car is, is there a standard that you're relying on that tells a manufacturer the risks that the manufacturer has to warn about associated with the device versus associated just with a procedure --
MR. KUNTZ: Objection.
THE WITNESS: I just --
BY MS. SUTHERLAND:
Q. -- other than the blue book memo?
A. I just read a few moments ago.
Q. Is it the ones you already stated?
A. Yes. Stating as well that based on my review of various documents, that for mesh, separating out the procedure from the device, and, in fact, talking about the procedure, FDA just had in February a panel meeting on reclassification of the instrumentation.
Q. I didn't ask you anything about reclassification.

A. That has to do with the procedure.
Q. The question is just on the standards.
A. Separating out the procedure and the device for these mesh products, I don't believe it's my opinion you can do that, and that all the hazards and any expected and foreseeable side effects should be included and any residual risk identified according to the standards as I discussed them.
Q. This really is the last question.
Is there a manufacturer that has met that standard in the pelvic mesh arena?
A. Because I haven't reviewed the information for every manufacturer, that type of information for every manufacturer in the mesh arena, I'm unable to answer that question.
Q. For the ones you have reviewed, how many have you reviewed?
A. Boston Scientific, Bard, and Ethicon, and certain products, not all products for every one of them.
Q. For the ones you have reviewed, none of them have met the standard you just set out?
A. That's correct.
MS. SUTHERLAND: That's it.
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EXAMINATION
BY MR. KUNTZ:
Q. I got one question real quick.
Dr. Pence, you have also reviewed numerous depositions from Ethicon internal employees, including Medical Directors Weisberg, Dr. Robinson, Pete Hanuel, and regulatory professionals, like Kathryn Breach; correct?
A. That's correct.
Q. Do they set forth in their testimony what they believe Ethicon or a manufacturer has to set forth in labeling?
A. Yes, they do.
Q. And to the best of your recollection, what do those individuals say needs to be put in IFUs in labeling with respect to adverse events?
A. Adverse reactions that are known, and there's testimony that says all of these adverse reactions were known from the start of the implementation of these products, as well as warnings and contraindications.
MR. KUNTZ: No more questions.
MS. SUTHERLAND: To be continued.
(Time noted: 11:45 a.m.)

DECLARATION UNDER PENALTY OF PERJURY
Case Name: AMSDEN VS. ETHICON
Date of Examination: March 9, 2016
Job No.: 125666
I, PEGGY PENCE, PH.D., hereby certify under penalty of perjury under the laws of the State of _____ that the foregoing is true and correct.
Executed this _____ day of _____, 20___, at _____.

_____
PEGGY PENCE, PH.D.

I, KRISTI JOHNSON, CSR No. 12585, Certified Shorthand Reporter, certify;

That the foregoing proceedings were taken before me at the time and place therein set forth, at which time the witness declared under penalty of perjury; that the testimony of the witness and all objections made at the time of the examination were recorded stenographically by me and were thereafter transcribed under my direction and supervision;

That the foregoing is a full, true, and correct transcript of my shorthand notes so taken and of the testimony so given;

( ) Reading and signing was requested.

( ) Reading and signing was waived.

(X) Reading and signing was not requested.

I further certify that I am not financially interested in the action, and I am not a relative or employee of any attorney of the parties, nor of any of the parties.

I declare under penalty of perjury under the laws of California that the foregoing is true and correct.

Dated this 14th day of March, 2016.

____

KRISTI JOHNSON, CSR No. 12585

EXAMINATION ERRATA SHEET

Case Name: AMSDEN VS. ETHICON

Name of Witness: PEGGY PENCE, PH.D.

Date of Examination: March 9, 2016

Job No.: 125666

Reason Codes: 1. To clarify the record.

2. To conform to the facts.

3. To correct transcription errors.

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EXAMINATION ERRATA SHEET

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_______ Subject to the above changes, I certify that the transcript is true and correct

_______ No changes have been made. I certify that the transcript is true and correct.

____

PEGGY PENCE, PH.D.